

## REMARKS

### I. Status of claims

Claims 1-5 and 7-13 are pending in this application. Claim 1 has been amended to replace "the fluorination of" with "fluorinating" in order to recite a process step. Claims 1, 4 and 11 have been amended to delete "phenyl" from the definition of  $R_1$ . Claim 1 has been amended to incorporate the subject matter of claim 6 which has been canceled. As suggested by the Office Action, claims 1, 4 and 10-11 have been amended to recite the Markush group "one or more substituents selected from the group consisting of halogen, hydroxy, amino, mono- or di- $C_1$ - $C_8$  alkylamino,  $C_1$ - $C_8$  alkyl,  $C_1$ - $C_8$  alkoxy and  $C_1$ - $C_8$  carbalkoxy." Support for this amendment can be found throughout the specification, particularly in the last paragraph on page 4 which shows that the phenyl can be substituted with one, two or three groups. Claims 5, 7, 9-10 and 13 have been amended to correct obvious typographical mistakes. No new matter has been added as a result of the amendments to the claims.

Consideration and entry of this response is respectfully requested. The response does not raise any new issues that would require any burdensome search by the Examiner and merely places the application into condition for allowance or in better form for consideration on appeal.

### II. Applicants' Statement of the Substance of the Examiner Interview of February 23, 2010

Applicants thank Examiner Sean Basquill for affording Applicants' representative Baltazar Gomez (reg. no. 61924) the opportunity to discuss the instant Application during the telephone interview of February 23, 2010. Applicants provide a timely Statement of the Substance of Examiner Interview in compliance with MPEP §713.04.

**A. Exhibits:** Not applicable.

**B. Claims:** 1 and 11-13.

**C. Prior art:** Not applicable

**D. Amendments:** Not applicable.

**E. Principal Arguments of Applicants and Examiner:** Applicants pointed out that the finality of the Office Action is improper because the Examiner presented a new rejection based on a new reference. The Examiner maintained that the finality of the Office Action was proper. Applicants also argued that the Examiner incorrectly interpreted the scope of the claims, particularly  $R_1$ . The Examiner maintained that  $R_1$  covers not only phenyl and substituted phenyl but also the various groups recited in the claims.

**F. Other pertinent matters:** The Examiner pointed out that Applicants' representative was not listed as having power of attorney for matters related to the instant application.

**G. General results:** The Examiner suggested that the claims be amended to recite the Markush group as proposed in the Office Action. Applicants agreed to file an Authorization to Act in a Representative Capacity naming practitioner Baltazar Gomez.

**H. Internet e-mail contents:** Not Applicable.

### **III. The Amendments to the Specification**

The specification has been amended to correct obvious typographical mistakes. The amendment on page 10 corrects errors in the chemical name of the compound prepared as described on that page. The stereodescriptor "β" is missing for the 11-position in the name, while the stereodescriptor "α" for the 16-position should obviously be "β." The above amendments are apparent because the reaction described on page 10 does not cause a change in the stereochemistry of the 11- or 16-position. As a result, the stereodescriptors for those positions are the same in both the starting material and the product as illustrated by the reaction scheme on page 10. In steroid chemistry, the stereodescriptor "β" refers to a substituent that is located above the plane of the steroid molecule. In the scheme on page 10, this is represented by the bold, wedge-shaped bonds at the 11- and 16-positions of the molecules. It is obvious from the scheme that both substituents in 11- and 16-position are "β" substituents.

No new matter has been added as a result of the amendments to the specification.

### **IV. Response to the claim objection and rejection under 35 U.S.C. § 112, second paragraph**

Applicants respectfully thank the Examiner for withdrawing the claim objections and the rejection under 35 U.S.C. § 112, second paragraph in light of the response filed July 6, 2009.

### **V. Response to the rejection under 35 U.S.C. § 102(b) and (e)**

The Office Action maintained the rejection of the claims as allegedly being anticipated.

Claims 1-3, 5-8 and 10-11 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by La Loggia (U.S. Pat. No. 6,794,503).

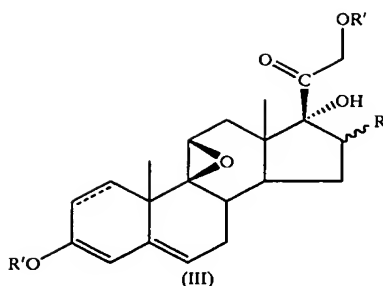
Claim 10 was rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by MacDonald (U.S. Pat. No. 4,255,331).

Claims 1-3 and 5-10 were rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by Chernyak (WO2003/047329).

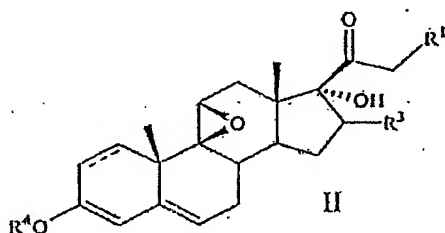
It is accepted law that "[a] rejection for anticipation under section 102 requires that each and every limitation of the claimed invention be disclosed in a single prior art reference." *In re Buszard*, 504 F.3d 1364, 1366 (Fed. Cir. 2007). With this in mind, Applicants respectfully submit that the cited references fail to anticipate the claims.

The process of claims 1-3, 5-9 and 11; as now amended, comprises fluorinating the formula II compound having an R<sub>1</sub>-C(O)-O- group at the 3-position wherein R<sub>1</sub> is a phenyl substituted with groups as recited in claim 1. Claim 10 is directed to the compounds of formula II.

La Loggia teaches fluorinating compounds of formula



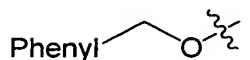
wherein R' in the 3-position is a carboxyalkyl group or acetoxy (at col. 2, lines 43-65 and col. 4, lines 18-25). Chernyak teaches fluorinating compounds of formula



wherein R<sup>4</sup> in the 3-position is C(O)-R<sub>d</sub> wherein R<sub>d</sub> is alkyl, aryl or heteroaryl, such as a phenyl, naphthyl, quinoliny, isoquininylinyl, or pyridyl (at paragraphs [0011] and [0026]). MacDonald teaches fluorinating compounds wherein the 3-position is substituted with acetoxy (at col. 1, lines 62-63). None of the cited references teaches fluorinating compounds substituted at the 3-position with a R<sub>1</sub>-C(O)-O- group wherein R<sub>1</sub> is a phenyl substituted with groups as recited in claims 1 and 10.

Each of the cited references fails to teach the process of claims 1-3, 5-9 and 11, at least because the references do not teach a process involving fluorination of a formula II compound. Each of the cited references also fails to teach the compound of claim 10 because the references do not teach a formula II compound.

Applicants note that the Office Action on page 3 asserted that Banerjee (21 *Synth. Comm.* (1991) 757) teaches benzoyl substituents at the 3-position. Applicants do not find such teaching in Banerjee. The Banerjee Abstract teaches "benzyl ether derivatives" for protecting 3 $\alpha$ -hydroxy groups. The scheme on page 759 of Banerjee teaches substituents "PhH<sub>2</sub>CO-" at the 3-position (compounds 9 and 11). The experimental examples on pages 766 and 768 for making compounds 9 and 11 use "benzyl bromide" as reagent. Based on the plain teaching in Banerjee, the substituent at the 3-position of the Banerjee compounds is a group of structure



The "benzyl ether" of Banerjee is not the substituent in the 3-position of formula II in the pending claims, which has the structure



Based on the above discussion, Applicant respectfully submit that the cited references do not anticipate the claims. Reconsideration and withdrawal of the anticipation rejection is respectfully requested.

#### **VI. Response to the rejection under 35 U.S.C. § 103(a)**

Claims 1-3, 5-10, and 13 were rejected under 35 U.S.C. 103(a) as allegedly being *prima facie* obvious over Chernyak.

Claims 1-3, 5-8, and 10-12 were rejected under 35 U.S.C. 103(a) as being *prima facie* obvious over La Loggia as in view of Bogert (U.S. Pat. 2,961,441).

To support a *prima facie* obviousness rejection, all words in a claim must be considered so that the claimed invention as a whole is compared with the cited references. MPEP §§ 2141.02, 2142, and 2143.03. In addition, the Board of Patent Appeals and Interferences has confirmed that a proper, post-KSR obviousness determination still requires the Office to make “a searching comparison of the claimed invention – *including all its limitations* – with the teaching of the prior art.” *Ex parte Wada and Murphy*, Appeal 2007-3733, at 7 (Bd. Pat. App. & Inter. 2008). Therefore, a *prima facie* obviousness rejection requires at least a suggestion of all of the claim elements.

As explained above, neither La Loggia nor Chernyak teaches or suggests fluorinating the formula II compound of claims 1 and 10 in which the group at the 3-position is an R<sub>1</sub>-C(O)-O- group wherein R<sub>1</sub> is phenyl substituted with groups as recited in the claims.

Thus, claims 1-3, 5-10, and 13 are not *prima facie* obvious in view of Chernyak because Chernyak fails to teach or suggest the claimed formula II compound or a process comprising fluorinating a formula II compound.

With respect to the rejection based on La Loggia, Applicants respectfully submit that Bogert does not cure the deficiencies of La Loggia. Specifically, Bogert teaches preparing 6 $\alpha$ - and 6 $\beta$ -fluorosteroids by fluorinating a compound that is not a formula II compound as recited in the pending claims. The Bogert compound has an acetoxy group at the 3-position. The combination of La Loggia and Bogert would fail to teach or suggest the claimed formula II compound or a process comprising fluorinating a formula II compound.

Thus, claims 1-3, 5-8 and 10-12 are not *prima facie* obvious in view of La Loggia and Bogert because the references fail to teach or suggest the claimed formula II compound or a process comprising fluorinating a formula II compound.

As demonstrated above, the cited references neither teach nor suggest all the claim limitations of the claims. The Office Action has not met the initial burden of factually supporting a *prima facie* conclusion of obviousness. Therefore, the present rejection has not established *prima facie* obviousness of the pending claims over the cited references. Applicants respectfully request withdrawal of the rejection under 35 U.S.C. § 103(a).

## VII. Response to the Obviousness-Type Double Patenting

The rejection of claim 10 as allegedly being obviousness-type double patenting over claims 1 and 6 of MacDonald was maintained. Applicant respectfully submits that claim 10 does not constitute obviousness-type double patenting. Claims 1 and 6 of MacDonald describe compounds wherein the 3-position is substituted with acetoxy, not with an  $R_1-C(O)-O-$  group wherein  $R_1$  is a substituted phenyl group as recited in claim 10. The methyl portion of the acetoxy substituent of MacDonald does not suggest a phenyl substituted with halogen, hydroxy, amino, mono- or di- $C_1-C_8$  alkylamino,  $C_1-C_8$  alkyl,  $C_1-C_8$  alkoxy or with  $C_1-C_8$  carbalkoxy. Accordingly, Applicants respectfully request reconsideration and withdrawal of the obviousness-type double patenting rejection.

## VIII. Conclusion

Applicant believes that claims 1-13 are in condition for allowance, and a Notice of Allowance is respectfully requested. The Examiner is invited to contact the Applicant's undersigned representative at (215) 293-6477 if the Examiner believes that this would be helpful in expediting prosecution of this application.

Respectfully Submitted,

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By: /Baltazar Gomez/  
Baltazar Gomez  
Reg. No. 61,924  
Teva Pharmaceuticals NA  
425 Privet Road | Horsham, PA 19044  
215.293.6477 phone | 215.293.6499 Fax  
baltazar.gomez@tevausa.com  
Customer Number 26646